K043065

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510(k) Summary

Submitter:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614-5686
Contact Person:	Jason Smith, Senior Regulatory Affairs Specialist
Date Prepared:	November 4, 2004
Trade names:	*Vigileo* Arterial Pressure Cardiac Output/Oximetry (APCO/Oximetry) Monitor Edwards Dual Disposable Pressure Transducer (DDPT)
Classification Name:	Monitor: Single-Function, Preprogrammed Diagnostic Computer (21 CFR 870.1435) Transducer: Extravascular Blood Pressure Transducer (21 CFR 870.2850)
Predicate Devices:	Monitor: *Vigilance* Continuous Cardiac Output/Oximetry/Continuous End Diastolic Volume (CCO/SvO_2/CEDV) Monitor Metracor RODA Monitoring System Transducer: Phoenix Disposable Pressure Transducer
Device Description:	The *Vigileo* APCO/Oximetry monitor is a microprocessor-based instrument which, when connected to a DDPT, continuously measures arterial pressure cardiac output (APCO). When connected to an Edwards oximetry catheter, the monitor measures oxygen saturation (oximetry). The monitor also calculates other derived parameters including cardiac index, stroke volume, stroke volume index, stroke volume variation, system vascular resistance, and systemic vascular resistance index.
Intended Use:	The *Vigileo* APCO/Oximetry monitor is intended to measure arterial pressure cardiac output and oximetry. The monitor also calculates hemodynamic and oxygenation parameters. The DDPT is intended to measure intravascular pressures. It is intended to transmit those pressure readings to both a standard blood pressure monitor and to the *Vigileo* monitor.
Comparative Analysis:	Both the *Vigileo* APCO/Oximetry monitor and the DDPT have been demonstrated to be as safe and effective as the predicate devices for their intended uses.

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Functional/Safety Testing:	Both the *Vigileo* APCO/Oximetry Monitor and the DDPT have successfully undergone functional testing as well as electrical safety testing. They have been shown to be equivalent to the predicate devices.
Conclusion:	The *Vigileo* APCO/Oximetry Monitor and DDPT are substantially equivalent to the predicate devices.

Jason Smith 11/4/04

Jason Smith
Senior Regulatory Affairs Specialist
Edwards Lifesciences LLC

Date

A C03

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 26 2005

Edwards Lifesciences LLC
c/o Mr. Jason Smith
Senior Regulatory Affairs Specialist
One Edwards Way
Irvine, CA 92614

Re: K043065
Trade Name: *Vigileo* APCO/Oximetry Monitor, Models MIHM1 and MIHM1P
Regulation Number: 21 CFR 870.1435 and 21 CFR 870.2850
Regulation Name: Single-Function, Preprogrammed Diagnostic Computer and Extravascular Blood Pressure Transducer
Regulatory Class: II (two)
Product Code: DXG and DRS
Dated: November 04, 2004
Received: November 05, 2004

Dear Mr. Smith:

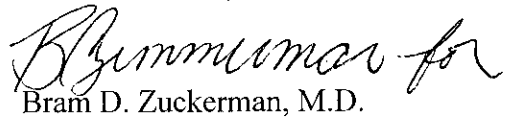
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: *Vigileo* APCO/Oximetry monitor

Indications for Use:

The *Vigileo* APCO/Oximetry monitor is indicated for use for continuously measuring hemodynamic parameters such as cardiac output and oximetry to assess oxygen delivery and consumption.

The Pressure Monitoring Kit with TruWave dual disposable pressure transducer is indicated for use in intravascular pressure monitoring. It is also indicated for use with Edwards pulse pressure based cardiac output monitoring devices or hardware to measure cardiac output.

Prescription Use __X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K043065